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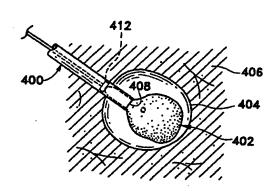
09/220,618 (CIP)

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[Continued on next page]

(54) Title: DEVICE AND METHOD FOR SAFE LOCATION AND MARKING OF A CAVITY AND SENTINEL LYMPH NODES



(57) Abstract: Cavity and sentinel lymph node marking devices, marker delivery devices, and methods are disclosed. More particularly, upon insertion into a body, the cavity marking device and method enable one to determine the center, orientation, and periphery of the cavity by radiographic, mammography, echogenic, or other noninvasive imaging techniques. A composition and method are disclosed for locating the sentinel lymph node in a mammalian body to determine if cancerous cells have spread thereto. The composition is preferably a fluid composition consisting of a carrier fluid and some type of contrast agent; alternatively, the contrast agent may itself be a fluid and therefore not need a separate carrier fluid. This composition is capable of (1) deposition in or around a lesion and migration to and accumulation in the associated sentinel node, and (2) remote detection via any number of noninvasive techniques. Also disclosed is a method for remotely detecting the location of a sentinel node by (1) depositing a remotely detectable fluid in or around a lesion for migration to and accumulation in the associated sentinel node and (2) remotely detecting the location of that node with a minimum of trauma and toxicity to the patient. The composition and method may serve to mark a biopsy cavity, as well as mark the sentinel lymph node. The marking methods also may combine any of the features as described with the marking device and delivery device.



- (74) Agents: BAGADE, Sanjay, S. et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).
- (81) Designated States (national): AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
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(AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

#### Published:

- With international search report.
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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A CLASSIFICATION OF SUBJECT MATTER
TPC 7 A51B17/00 A51B A61B8/00 A61B19/00 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B Documentation seasoned other than minimum documentation to the extent that such documents are included in the Belde seasoned Electronic date base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, INSPEC C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. WO 98 47430 A (VASCULAR SCIENCE INC) 1,7-12, 61-63 29 October 1998 (1998-10-29) 3.25-40. page 5, line 11 -page 6, line 14 51,52,60 page 8, line 30 -page II, line 34; figures
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Boxi	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	mational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: 130-220 because they relate to subject matter not required to be searched by this Authority, namely:
	Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. X	Claims Nos.: 13-22, 64,73-78 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
	see FURTHER INFORMATION sheet PCT/ISA/210
з. 🗌	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Bax II	Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)
This later	mational Searching Authority found multiple inventions in this international application, as lollows:
	see additional sheet
1. X	As all required additional search (see were timely paid by the applicant, this international Search Report covers all searchable claims.
2	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional tee.
3.	As only some of the required additional search fass were timely paid by the applicant, this international Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Flormark o	The additional search tres were accompanied by the applicant's protest.
	X No protest accompanied the payment of additional search fees.

# FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-12,23-59, 61-63

marking device of resilient bioabsorbable material with a marker

2. Claim: 60

marking device of nonbioabsorbable suture material and marker

3. Claims: 65-78,221,222

composition comprising nontoxic detectable microparticles

4. Claims: 79-83,126,129

marking delivery device with cartridge

5. Claims: 84,85-93,123,125,127,129

marking delivery device with outer sheath for use with amedical instrument

6. Claims: 84,94-118,129-122,124,125,128,129

marking delivery device with a flexible shaft protion

7. Claims: 84,119

marking delivery device preloaded with a marking device

8. Claim: 223

process for making a marking device by placing a marker on a sheet

9. Claims: 224,225

process of making a marking device by cutting a filler body and creating a hole therein.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box 1.2

Claims Nos.: 13-22, 64,73-78

Claims 13 to 22 and 64 and so the claims 73-78 (dependent on claim 64) are not clear (in the sense of Article 6 PCT) in that they do not define device features, but define a device merely by results to be achieved when using the device. In particular, it is unclear how the device is restricted by the mere desiderata of the body is "palpable" and "degradable" over some periods of time.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

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